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14. ABSTRACT

Purpose: To examine the effects of ubiquinol (reduced form of Coenzyme Q10) in leukocytes, lungs, diaphragm, and microcirculation following hemorrhagic shock (HS) Design: Experimental. Methods/Instrumentation: Anesthetized rats were bled to induce HS by removing 40% of the blood volume over 60 minutes. The rats were resuscitated with blood and lactated Ringer's solution, with or without ubiquinol, and monitored for 120 minutes. Lungs and diaphragm were excised and harvested for hydrogen peroxide (H2O2) concentration and apoptosis analysis. Leukocytes were analyzed for mitochondrial superoxide (O2) at baseline, end of shock, and 120 minutes following fluid resuscitation. In another set of experiments, leukocyte adherence and mast cel Sample: Sprague Dawley male rats were used and randomly assigned to the control or experimental groups. There were 10 rats per group in each set of experiments. Analysis: Statistical significances were defined at a p ≤ 0.05. Various types of nonparametric statistics were used. Findings: Mitochondrial leukocyte O2 in the control group increased and there was a 30% rise at the end of the experiment, as compared to ubiquinol group. Similarly lung and diaphragm apoptosis in the control group was significantly higher. Diaphragmatic H2O2 in the control group was also significantly higher than the ubiquinol group. There were significant differences in leukocyte adherence, the MCD index, vascular permeability and microcirculation ROS production between the control and the ubiquinol groups. I degranulation (MCD) was obtained. Vascular permeability was assessed and reactive oxygen species (ROS) in the venular walls were determined. Implications for Military Nursing: Ubiquinol is a safe and easily administered supplement that prevents damage and reperfusion injury following HS. Attenuating damage to organs with the use of ubiquinol following HS could be used in military personnel.

15. SUBJECT TERMS

pneumonia, mechanical ventilator, chlorhexidine, critical care

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FINAL REPORT

Abstract

Purpose

This randomized, controlled clinical trial tested an early (within 12 hours of intubation) application of chlorhexidine (CHX) by swab versus control (no swab) on oral microbial flora and ventilator-associated pneumonia (VAP).

Method

A total of 145 trauma patients requiring endotracheal intubation were randomly assigned to either the intervention (5 ml CHX) or control group. Oral microbial flora from semi-quantitative oral cultures and VAP (assessed by clinical pulmonary infection score [CPIS]) were obtained on study admission and at 24 (oral culture data only), 48, and 72 hours after intubation. The traumainjury and severity score (TRISS), severity of illness (APACHE III), and frequency of usual oral care were also recorded. A repeated-measure, proportional odds model tested for differences in the oral cultures between the groups, and a repeated-measures, random effects model tested for differences in CPIS, with CPIS greater than 6 indicating VAP.

Results

Of the 145 patients, 71 and 74 were randomized to intervention and control, respectively. Patients were 70% male and 60% white. Mean age was 42.4 years, and mean APACHE III score was 66. There were no significant differences between groups at study admission for any clinical characteristic except CPIS scores (5.05 [\pm 0.28] for intervention vs. 3.98 [\pm 0.27] for control, p < .01) and percentage of positive oral cultures (18.3% intervention versus 5.6% control, p < .01). No significant treatment effect (p = .33) on oral cultures was found. However, a significant treatment effect (p = .0233) on CPIS from admission to both 48 h and 72 h was found.

Conclusions

Because 41.7% of the control patients with a baseline CPIS less than 6 (no VAP) had developed VAP by 48 or 72 hours vs. only 19.4% of the corresponding intervention patients, this study showed that a single dose of CHX early in the intubation period is effective in reducing early VAP, especially in trauma patients without pneumonia at intubation.

Introduction

Ventilator-associated pneumonia (VAP) occurs most often in trauma, burn, and surgical patients. Reduction of oral bacteria associated with VAP reduces the pool of organisms available for translocation to the lung. VAP reduction occurs with repeated chlorhexidine (CHX) dosing, but use of a single dose has not been studied. This randomized, controlled clinical trial tested an early (within 12 hours of intubation) application of CHX by swab versus control (no swab) on oral microbial flora and VAP. VAP is responsible for 90% of nosocomial infections in the mechanically ventilated population. Growth of potentially pathogenic bacteria in dental plaque provides a nidus of infection for microorganisms that have been shown to be responsible for the development of VAP. Organisms associated with VAP colonize the oral pharynx of the critically ill patient prior to the VAP diagnosis. Therefore, reduction of organisms in the oral cavity using CHX immediately after intubation may reduce the incidence of VAP.

Scope of the Study

The **primary aim** of this study was to test the effect of a peri-intubation oral intervention on oral microbial flora in traumatic injury. A **secondary aim** was to test the effect of a peri-intubation oral intervention on the development of VAP in traumatic injury.

Research Plan

The study was a randomized, two-group (intervention and control) clinical trial of a single periintubation (within 12 hours of intubation) intervention consisting of application of CHX (0.12% solution) by swab to the oral cavity immediately following endotracheal intubation in adult trauma victims. Subjects were enrolled at the time of intubation in the emergency department.

The intervention was administered only by study personnel so that care providers could focus on the subjects' immediate needs rather than be responsible for any part of the study intervention.

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Subjects remained in the study for 72 hours after intubation or until extubation if extubated before 72 hours. The length of participation for subjects was chosen based on the length of time of increased risk of development of early VAP following intubation (Schwartz et al., 1978) and data concerning the length of efficacy of a single CHX intervention from our pilot studies and other populations (van Lunsen, de Soet, Weerheijm, Groen, & Veerkamp, 2000; Carret et al., 1997). Schwartz and colleagues (1978) found in acutely ill patients requiring prolonged orotracheal intubation that acquisition of Gram negative organisms in the trachea occurred by day 3. Cardenosa Cendrero et al. (1999) found that 80 of 110 patients had tracheal colonization during the first day of mechanical ventilation. A peri-intubation oral intervention will likely have its greatest effect on the incidence of early colonization and early VAP.

Setting

The study was conducted at Virginia Commonwealth University Health System (VCUHS), a 772-bed tertiary care university medical center that serves as the teaching hospital of Virginia Commonwealth University. The hospital, located in Richmond, Virginia, has been designated a level I trauma center for central Virginia. Approximately 54% of hospital admissions are African American and 41% are white (2000 VCUHS data).

Sample

Patients were randomized to either a treatment group or control group (usual care) using a block randomization scheme. The block size varied so that the research nurses would not be able to predict the next group assignment. The sample of 160 patients was drawn from all trauma patients over the age of 18 years admitted to the emergency department at VCUHS who required endotracheal intubation and were mechanically ventilated. Patients who were intubated in the emergency department, in the field, or en route to the emergency department were eligible for

enrollment if they were enrolled within 12 hours of intubation. For intervention group subjects, both the oral culture and the intervention were to be completed within 12 hours; for control subjects, the oral culture was to be completed within 12 hours of intubation. The actual time and location of intubation were retrieved from the medical record. Both male and female subjects from all ethnic and racial backgrounds were recruited. Because subjects were randomly assigned to the intervention or control group, it was anticipated that the number of subjects intubated for 24, 48, or 72 hours would be equivalent in each group. That assumption was to be verified prior to data analysis, and statistical adjustments were to be made if the groups were not equivalent in length of mechanical ventilation.

Exclusion criteria. The exclusion criteria were previous endotracheal tube placement in the last 48 hours or a diagnosis of pneumonia at the time of intubation. Those who had previous intubation in the last 48 hours were excluded because re-intubation has been shown to be a significant risk factor for the development of VAP (Cook et al., 1998), thus making it more difficult to demonstrate the effect of the intervention versus the effect of a previous intubation. Those who had a diagnosis of pneumonia at the time of intubation were excluded because a new episode of superimposed VAP cannot be distinguished with certainty from worsening of the patient's initial community-acquired or nosocomial pneumonia. Patients with burn injuries were also excluded because it would be difficult to discriminate inhalation injury from VAP using the Clinical Pulmonary Infection Score (CPIS), which includes changes in the chest x-ray.

Method

Peri-intubation oral intervention

The pharmacologic oral care intervention involved administration of CHX solution (0.12%) by swab (2 ml) to the oral cavity within 12 hours of intubation (Burtner, Smith, Tiefenbach, & Walker, 1996). Although CHX is used primarily as a mouthwash or rinse, it has also been used by swab and found to be equally effective (Stiefel, Truelove, Chin, Zhu, & Leroux, 1995; Stiefel, Truelove, Chin, & Mandel, 1992). CHX was stored in a dark bottle. Two ml was measured using a syringe from a small amount that had been poured into a medicine cup. Only this measured amount was placed in an empty measuring cup for soaking into the swab. Foam swabs (toothettes) were used to apply the CHX. Using a standardized protocol, all areas of the oral cavity were covered, including the anterior and posterior pharynx, gums, teeth, tongue, and buccal mucosa. This procedure was tested in our pilot study and was found to provide adequate coverage of all surfaces and to consistently reduce potential pathogens in the oral cavity. Because intubated patients cannot manage their oral secretions, use of the smallest amount possible that is effective and still covers all surfaces is best. CHX has bactericidal properties against both Gram positive and Gram negative species (Micromedex, 1999). Because it is not absorbed through skin or mucous membranes, dosage adjustments are not necessary to avoid renal or hepatic insufficiency. CHX administered by oral swab or rinse has not been associated with serious side effects (Stiefel, Truelove, Chin, Zhu, et al., 1995; Owens, Addy, Faulkner, Lockwood, & Adair, 1997; Elworthy, Greenman, Doherty, Newcombe, & Addy, 1996). Reported side effects include discoloration of the teeth and tongue and transient alterations in taste (dulling of taste sensation for several hours). Discoloration of the teeth occurs in about 50% of patients with long-term administration and is similar to the tooth staining seen after smoking

and consumption of tannic acids such as tea, coffee, and wine. However, the use of a single dose of CHX as in this study is not likely to result in any tooth staining.

Usual care

The control group had standard endotracheal intubation care based on the hospital's emergency department protocol. After intubation, ICU (intensive care unit) staff nurses provided oral comfort care for all subjects (control and intervention groups) as per their usual practice. Data related to frequency and type of oral comfort measures provided by ICU nursing staff were documented from nurses' entries on the ICU flow sheet. The ICU flow sheet contains an oral care column that nurses check each time they provide oral care. Our preliminary data (Study #1 in the preliminary study section) show that oral care practices do not differ between the STICU (shock and trauma ICU) and NSICU (neurosurgical ICU). Presently, respiratory therapy equipment and care is standardized across the two units (STICU, NSICU) where trauma victims are located, and these standards were continued throughout the study period. Changes in the standards that occurred during the study period were applied to all units at the same time. Any changes in respiratory therapy care were documented by the research team. Disposable equipment was not reused. Medication chambers, ventilator tubing, and nebulizers were changed every 24 hours, and all humidifiers were changed every 48 hours. Condensed water in the tubing was drained away from the patient. Ultra-high efficiency filters were used on the main flow inspiratory line. Ventilator breathing circuits were not changed unless soiled or nonfunctional. In-line, closed-system suctioning systems were used for all subjects and were maintained based on unit protocol.

Key Variables and Their Measurement

Oral Microbial Flora. Cultures of oral microbial flora were evaluated using a microscopic examination (Gram stain) and semiquantitative culture with standard techniques by VCUHS's Clinical Support Laboratory (). The laboratory personnel who analyzed cultures were blinded to the subject's group assignment. Gram staining is widely recognized as the simplest, least expensive, and most useful of all rapid methods used to identify the presence and morphologic features of microorganisms and thus identify bacterial pathogens. Culture growth on media selective for VAP pathogens, including Staphyloccocus aureus, Streptococcus pneumoniae, Acinetobacter baumannii, Haemophilus influenzae, and Pseudomonas aeruginosa, were categorized as 1 (no growth/few organisms), 2 (moderate organisms), or 3 (many organisms). This categorization results in ordinal data with categories similar to those used for evaluation of cultures from endotracheal tube secretions and calculation of the CPIS. Semiquantitative scoring permits the differentiation of colonization (score of 1) from infection (score of 2 or 3) (Ioanas, Ferrer, Angrill, Ferrer, & Torres, 2001) and for this reason is considered superior to qualitative culture techniques (Waterer & Wunderink, 2001). Because a semiquantitative culture enables documentation of changes in amounts of microbial flora, it is routinely used in the clinical setting. Oral cultures were obtained using a sterile culturette swab. The oral cavity was swabbed in the following order, using a single swab: buccal gingival margin (obtaining organisms from gum line and tooth surface), buccal mucosa, and palate. Oral cultures were obtained on subjects in both the control and intervention groups on admission to the study (prior to the intervention) and at 24, 48, and 72 hours.

Development of VAP. VAP has been defined as pneumonia occurring in a mechanically ventilated patient that was neither present nor developing at the time of intubation; thus, clinical evidence of VAP occurs 48 hours or more after intubation (Kollef, 1999; Meduri, 1993). The CPIS, developed by Pugin et al. (1991) and used by others (Cook, Walter, et al., 1998; Yende & Wunderink, 1998) is based on six easily obtained variables (Table 6): temperature, WBC (white blood cell) count, tracheal secretions, oxygenation (calculated by PaO₂/FiO₂), chest radiograph (from the radiologist's report), and tracheal aspirate culture. The tracheal secretions score, which is an estimation of the total secretions per day, is calculated based on the nurse's estimate of the quantity of secretions from 0 to 4 (none, scant, small, moderate, large, as routinely documented on the ICU flowsheet) for each aspiration and then totaled for a 24-hour period. The tracheal aspirate culture was evaluated using a microscopic examination (Gram stain) and semiquantitative culture of endotracheal secretions. Each variable is assigned points, and a total CPIS is obtained (range: 0 to 12).. Because points are given for processes that may eventually result from VAP (e.g., increasing WBC count, temperature, infiltrate, and amount of tracheal secretions), a range of scores results. Therefore, the use of the CPIS enables a description of the development of VAP over time, enhancing the ability to describe the effect of a peri-intubation oral intervention on the development of VAP. Several previous studies (Pugin et al., 1991; Papazian et al., 1995; Abele-Horn et al., 1997; Cook, Guyatt, et al., 1998; Cook, Walter, et al., 1998) have used the range of CPIS scores to describe the clinical development and progression of pulmonary infection as well as a designated level (score of 6 or greater) for diagnosis of VAP.

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Additional Data Collection

<u>Trauma/Injury and Illness Severity</u>. General severity scoring systems allow for the scientific and quantitative description of groups of critically ill patients, although they cannot accurately

predict individual patient outcomes () Two severity scoring systems (TRISS [Trauma and Injury Severity Score] and APACHE III) were used to determine the equivalence of the intervention and control groups with respect to level of trauma/injury and severity of illness.

Other risk factors. Administration of antibiotics prior to entry into the study was defined according to the definition used in other studies (Kollef, 1993; Rello, Ausina, Ricart, Castella, & Prats, 1993; Rello et al., 1994; Kollef, 1994; Beck-Sague et al., 1996), as any antimicrobial agent received for 48 hours or longer, within 10 days prior to the development of VAP. Trauma victims may be taking antibiotics for other reasons that may then place them at risk for VAP after injury. The specific drugs and dosage information were recorded.

Procedures

The research nurses completed the collection of all admission data, including the subject's age, sex, ethnic background, TRISS, severity of illness score (APACHE III), administration of antibiotics prior to entry into the study, type of intubation (oral vs. nasal), and teeth decayed, missing, or filled (DMF). All baseline clinical data were collected at the time of enrollment, including components for the CPIS and results of the oral cultures. Baseline oral cultures were obtained prior to administration of the intervention. Baseline endotracheal aspirate specimens (for CPIS) were also collected on study admission. VCUHS Clinical Support Laboratory personnel who analyzed the cultures were blinded to the subject's group assignment.

Endotracheal aspiration of sputum for culture and Gram stain (for the CPIS) was obtained using a single-use sterile catheter based on hospital procedure (no saline was used) and was obtained when the patient required endotracheal tube suctioning as close to the required time frame as possible. Oral cavity cultures were obtained using the standardized method validated with the

R15 study and described above (Key Variables and Their Measurement). Both endotracheal and oral specimens for culture and sensitivity as well as Gram staining were transported to VCUHS's Clinical Support Laboratory by the research nurse. The Clinical Support Laboratory has extensive experience in processing and analyzing clinical specimens, has appropriate quality assurance programs in place, and is fully accredited by the College of American Pathologists.

Data Analysis

Table 1. Recruitment and Retention

If this does not apply to your study, check here

	Projected original pr		Actual #		
# subjects available	7575 (hosp	adm)	2369 (ICU adm)		
# subjects contacted					
# subjects screened			505		
# subjects refused			52		
# subjects consented			152		
Intervention/Control			74	78	
# subjects enrolled					
Intervention/Control			74	78	
# subjects dropped out					
Intervention/Control			3	4	
# subjects completed					
intervention					
Intervention/Control			71	74	

Results/Discussion

Results

Of the 145 patients, 71 and 74 were randomized to intervention and control, respectively. Patients were 70% male and 60% white. Mean age was 42.4 years (\pm 18.2); mean APACHE III score was 66 (\pm 29.8). There were no significant differences between groups at study admission for any clinical characteristic except in CPIS scores (5.05 [\pm 0.28] for intervention vs. 3.98 [\pm 0.27] for control, p < .01) and percentage of positive oral cultures (18.3% for intervention group

versus 5.6% for control, p < .01). No significant treatment effect (p = .33) on oral cultures was found. However, a significant treatment effect (p = .0233) on CPIS from admission to both 48 h and 72 h was found.

Discussion

One of the most critical risk factors for the development of nosocomial pneumonia in intubated patients is colonization of the oropharynx (Fourrier, Duvivier, Boutigny, Rourrel-Delvallez, & Chopin, 1998; Garrouste et al., 1997). Growth of potentially pathogenic bacteria in dental plaque provides a nidus of infection for microorganisms that have been shown to be responsible for the development of VAP (Fourrier et al.; Scannapieco, Stewart, & Mylotte, 1992). Initial tracheal colonization is most likely related to the passage of microorganisms from the oropharynx to the trachea during intubation (Schwartz et al., 1978; Rubenstein, Kabat, Shulman, & Yogev, 1992). The vast majority of organisms that are associated with VAP (including S. aureus, S. pneumoniae, A. baumanii, H. influenzae, and P. aeruginosa) have been found to colonize the oral pharynx of the critically ill patient prior to the VAP diagnosis (Cardenosa Cendrero et al. 1999). In addition, several factors increase bacterial colonization of the oropharynx in the mechanically ventilated critically ill patient after intubation. Within 48 hours of hospital admission, the composition of the oropharyngeal flora of critically ill patients undergoes a change to predominantly Gram-negative organisms, constituting a more virulent flora, including potential VAP pathogens (Abele-Horn et al. 1997; Johanson, Seidenfeld, de los Santos, Coalson, & Gomez, 1988). After intubation, the endotracheal tube provides a pathway for direct entry of bacteria from the oropharynx through an open glottis to the lower respiratory tract. Therefore, reducing the number of microorganisms in the mouth reduces the pool of organisms available for translocation to and colonization of the lung.

This study showed that a single early application of CHX administered to the oral cavity within 24 hours of intubation can significantly reduce the development of VAP. This simple, efficient, and economical intervention may have great impact on reducing the complications associated with intubation using an endotracheal tube and with mechanical ventilation in the trauma population.

Conclusion and Implication

Because 41.7% of the control patients with a baseline CPIS less than 6 (no VAP) had developed VAP by 48 or 72 hours, versus only 19.4% of the corresponding intervention patients, this study showed that the use of a single dose of CHX early in the intubation period is effective in reducing early VAP, especially in trauma patients without pneumonia at intubation. However, very few positive oral cultures were observed in this study, making it difficult to find changes in this outcome across time or between the groups.

Significance of Research to Military Nursing

Oral health status, which has a profound effect on general health, is influenced by the microbial flora of the individual. The Surgeon General's Report on Oral Health in America (September 2000) identifies a "silent epidemic" of dental and oral disease (U.S. Department of Health and Human Services, 2000). Among those who suffer the worst oral health are poor Americans and members of racial and ethnic minorities. Of interest is the fact that the 1994 Tri-Service Comprehensive Oral Health Survey (TSCOHS), a 30-site study of the oral health of almost 16,000 U.S. Army, Navy, Marine Corps, and Air Force active duty personnel and recruits, documented that compared with their civilian cohorts, military recruits had a higher proportion

of decayed teeth and a lower annual use of dental care. Nearly all (99.3%) recruits needed some type of dental care. Combat soldiers, especially recruits, are particularly vulnerable to dental decay because dental hygiene tends to decline during deployment or during field training exercises for prolonged periods. Away from the familiar, and likely more nutritious, meals of home, the consumption of high-sugar foods tends to increase. The combination of a high-sugar diet and poor dental hygiene provides an environment in which oral bacteria flourish.

Combat casualty care includes treatment of blunt and penetrating trauma and burn and blast injuries, often requiring airway stabilization with endotracheal intubation (Bellamy, Maningas, & Vayer, 1986; Bellamy, 1984; Carey, 1996; Behbehani, Abu-Zidan, Hasaniya, & Merei, 1994; Brundage, Kohlhase, & Rubertone, 2000; Blood, Gauker, Jolly, & Pugh, 1994). The Army's Medical Reengineering Initiative includes a goal of stabilizing and removing combat casualties from the battlefield as quickly as possible. Airway stabilization and endotracheal intubation frequently occurs in a field setting. Therefore, combat soldiers who have poor dental hygiene and require endotracheal intubation in the field and prolonged mechanical ventilation due to traumatic injury will be particularly at risk for increases in oral microbial flora and therefore VAP. Accordingly, this single early application of CHX to the oral cavity within 12 hours after endotracheal intubation may reduce the risk for VAP in this vulnerable population.

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Outcomes Resulting From Study:

Abstract submitted for presentation at the American Association of Critical Care Nurses National Teaching Institute in May 2009. Review of the abstract is in process. Publication of full study results will be submitted in early 2009.

APPENDIX A

Proposal No.: N03-006

Final Budget Report

CATEGORY	ORIGINAL AWARD	REALLOCATIONS	AT END OF STUDY	REMAINING AMOUNT
Personnel	\$262,777	\$115,362	\$403,768	-\$25,629
Consultant	\$0	\$0	\$0	\$0
Equipment	\$0	\$0	\$0	\$0
Pharmacy/Pathology	\$34,220	\$588	\$21,014	\$13,794
Travel	\$1,800	\$1,800	\$4,745	-\$1,145
Patient Care Costs	\$0	\$0	\$0	\$0
Other Expenses	\$1,097	\$0	\$1,474	-\$377
Facilities/ Administration	\$149,948	\$58,879	\$208,827	\$0
TOTAL	\$449,842	\$176,629	\$639,828	-\$13,357

Discussion:

The over expenditures, totaling \$13,357, have been covered by the Virginia Commonwealth University School of Nursing to complete the project.

VCU Grants and Contract Department will mail a final expenditure report to DOD on October 31, 2008.

APPENDIX B

Problems Encountered, Resolutions

No significant problems were encountered other than slower enrollment than expected. It was difficult to enroll subjects within the tight time frame (i.e., within 12 hours of intubation) without 24-hour, 7-day-a-week research assistance support, as we were unable to contact every potential subject. However, we did obtain a sample very close to the projected number and did find a significant difference between the intervention and control groups.

APPENDIX C

Proposal No.: N03-006

Psychometric Report

Reliability and Validity of Measures										
If no instrumentation was used for your study, check here										
<u>Directions</u> : Please complete the questions below addressing demographic characteristics of your sample										
and overall	sample size.	For the too	l identifi	ied in th	ne attac	hed co	over letter, p	lease complete the follo	owing	
questions re	garding any	reliability a	nd/or va	lidity t	esting y	you pe	rformed. Ple	ease note that this list is	not	
meant to be	meant to be exhaustive. If you performed other reliability and/or validity testing which is not listed, please									
identify the	test, and rep	ort your fin	dings un	der "ot	her." If	furthe	er space is no	eeded, please attach add	litional	
pages. Pleas	se submit a c	opy of the t	ool if yo	ou made	any m	odific	ations.			
I.	Principal	Investigat	or – Co	ntact	Inforn	natior	1			
Name:	Mary Jo Gr	rap			Telep	hone			Work	
Address:					Numb	er:			Home	
					E-mai	1:				
Title of	A Peri-Intu	hation Inter	vention	to Redu	ice Ora	ıl Flora	and VAP			
Study	A I en-mu	oation inter	vention	io Redi	ice Ora	11 11016	t allu VAI			
Demograpl	nic Characto	eristics of S	Sample							
Total sampl	a ciza:	Age	42 (range 18-88		ge 18-88)					
Total Sampi	c size.	Range:					Number	Service		
	<19 yrs	19-60	>60 yrs	s Other			0	Army		
	(1) J15	yrs	/00 y18 Ot		1101		O .			
Male	2	86	13	0			0	Air Force		
Female	2	36	8	0			0	Navy	vy	
							0	Marine		
Number	Race:			_			Number	Service Component:		
87	Caucasian						0	Active Duty		
55	African-American						0	Retired		

Principal Investigator: Mary Jo Grap

		Counted as					
2	Hispanic (ethnicity)	white for	0		Reserve		
		race					
1	Asian/Pacific Islander		0		National Guard		
2	Other (Describe)		0		Dependent		
Briefly desc	Briefly describe defining characteristics of sample:						
The sample was 30% female and 70% male and representative of the ICU trauma population (62% STICU,							
38% NSICU). Duration of mechanical ventilation was a mean of 5.05 days. The majority (78%) were							
intubated for airway control or altered mental status. Most were intubated either in the field or in the							
Emergency Department (59%) or in the ICU 17%.							

Proposal No.: N03-006

Instrument Reference – N/A							
Instrument Title:	N/A				Numb	er of	
instrument Title.					Scales	: :	
Instrument					Editio	n:	
Publication Year:							
Authors:							
Publisher:							
Journal or Book							
Title:							
Year:		Volume:		Page Numbers:			
Tool Modifications							
Did you modify this	tool?	☐ Yes (Ans	swer A & B below)	□ No			
A. Briefly describe	why						
modifications were made:							
B. Describe what							
modifications were made							
(attach page if additi	onal						
space is needed):							

Principal Investigator: Mary Jo Grap

Directions: Please indicate any reliability and/or validity testing you did on this instrument. Please report
findings of each scale next to the test.

Check all that apply

Reliability		Validity			
Internal-Consistency Reliability		Content Validity			
☐ Cronbach Coefficient Alpha		☐ Index of Content Validity (CVI)			
☐ Kuder- Richardson (KR-20)		☐Other (please describe on back of form)			
☐ Interraterr Reliability		Criterion-Validity			
☐ Intrarater Reliability		☐ Predictive			
☐ Coefficient of Stability (test-ret	est)	☐ Linear Correlation			
☐ Coefficient of Equivalence		Name of Criterion Measure Used:			
☐ Other (please describe on back	of form)	Concurrent			
		☐Linear Correlation			
Reliability of Individual Scales		Name of Criterion Measure Used:			
Scale Name	Reliabilit y	☐ Construct Validity (include a copy of findings)			
		☐ Multitrait-Multimethod			
		☐ Hypothesis testing			
		☐ Contrasted Group			
		☐ Factor Analysis			
		☐ Exploratory			
		☐ Confirmatory			
Please use back of form for addition	onal scales	☐ Other (please describe on back of from)			
Evaluation of Measure					
Would you recommend the use of	this measure in	your population to other researchers? Use extra page,			
if needed.					
☐ Yes. Please explain					
why.					

☐ No Please explain	
why.	

APPENDIX D

Research Categorization Using TSNRP Areas of Research

Identify the main research priority investigated in this research study. Please check one item for Primary (Required) and one item for Secondary Priority Areas (if appropriate). Primary Research Priority Area: (Required) ___ Military Deployment Health _X__ Translating Knowledge & Research Findings into Practice in a Military Context _X__ Evidence Based Practice ____ Recruitment & Retention of the Military Nursing Workforce ____ Developing & Sustaining Military Nursing Competencies Secondary Research Priority Area: _X_ Military Deployment Health ____ Translating Knowledge & Research Findings into Practice in a Military **Evidence Based Practice** ____ Recruitment & Retention of the Military Nursing Workforce Developing & Sustaining Military Nursing Competencies Other (fill in) Identify 3-5 key words relating to the proposal. (Required) (You MUST use the CRISP Thesaurus for key words. The thesaurus is on the web at: http://crisp.cit.nih.gov/crisp/crisp_help.help pneumonia mechanical ventilator chlorhexidine critical care

Principal Investigator: Mary Jo Grap	Proposal No.: N03-006		

APPENDIX E

Do you have any articles or presentations 'in press'	yes	⊠ no
If yes, provide copies and all PAO clearance information.	All citat	ions listed must be in
APA format.		

APPENDIX F

Public Affairs Office Clearances

See clearance on page 20.